HIV Prevention Counseling, Rapid Testing and Referral Services Quality Assurance and Procedural Protocol

I. DESCRIPTION OF THE INTERVENTION

A. The HIV Prevention Counseling, Rapid Testing, and Referral Services intervention involves one-on-one, client-centered, risk/harm reduction counseling sessions coupled with antibody screening for HIV; whereby both test results and appropriate referrals to other services are provided to clients during the same visit. The rapid (same visit results) HIV testing component of the intervention can only be conducted in community settings using a FDA approved and CLIA-waived rapid HIV test devices. "CLIA" stands for the Clinical Laboratory Improvement Amendments, which represents federal legislation and an oversight administration that governs and classifies all diagnostic tests performed on human subjects according to each test's level of operating difficulty.

B. The State of Louisiana standards for HIV Prevention Counseling, Rapid Testing and Referral Services (abbreviated as CRT for the remainder of this protocol) are based on the integrated National Centers for Disease Control and Prevention's (CDC) HIV prevention counseling and rapid testing models, which empower clients to assess their readiness for results, their own risk behaviors and to develop a realistic and incremental plan for behavior change. More information regarding the CDC guidelines for HIV prevention counseling can be found in the *Revised Guidelines for HIV Counseling, Testing, and Referral,* (MMR, 2001). More information on CDC guidelines for rapid HIV testing can be found in the *Quality Assurance Guidelines for Testing Using Rapid HIV Antibody Tests Waived Under the Clinical Laboratory Improvement Amendments of 1988,* (MMR, 2007). Both documents are located on the CDC's website (www.cdc.gov).

II. PREREQUISITES TO IMPLEMENTING CRT

This section covers what must be done to assure the proper functioning of the rapid HIV test and to generally prepare an agency for implementing the CRT intervention. Before CRT can be performed, prerequisites related to physical testing sites, testing supplies, quality assurance and personnel must be satisfied.

1. Prerequisites for CRT Sites

1. CRT conducted by CBOs is reserved for high-risk areas as outlined in the Statewide Prevention Plan and regional disproportionately impacted zip codes. CBOs under contract with SHP should maintain/establish CRT sites in areas that have been identified by the Regional Prevention Coordinator as belonging to one of the disproportionately impacted zip codes in the area or identified as a site of particular importance/appropriateness for HIV prevention activities (such as a site with a history of at least 1% new positivity among individuals tested, a site where high risk activities occur such as commercial sex work, etc. or a site where individuals belonging to high risk groups are known to congregate).

2. All sites must be assessed and approved by SHP before CRT can be conducted. Agencies conducting CRT must register both fixed and mobile sites through the SHP Regional Coordinator or other SHP prevention staff using the Site Assessment and Registration Form (see Attachments RT-6). SHP staff will visit each potential site to determine if it is appropriate for rapid testing activities. Please allow up to four (4) weeks to process the Site Assessment and Registration Form. SHP will assign a unique site number and site type code for the new site and mail a certificate of approval for CRT back to the requesting agency once the registration process is complete.

3. Agencies conducting CRT must yield at least a one-percent (1%) newly identified positivity rate annually. The percent positivity is defined as the total number of newly identified positive HIV tests, divided by the total number of tests conducted by the agency and multiplied by one hundred.

4. SHP staff is required to be in attendance during the agency's first day of CRT implementation.

5. All CRT sites must provide a private, confidential setting for HIV prevention counseling to occur. Crucial elements of a confidential setting include:
    i. Ample space for a private conversation to occur.
    ii. Secluded area for counseling session.
    iii. Support from site staff to respect privacy of clients.

6. Agencies providing any CRT are required to post a sign in their reception area stating the age limitations for testing and provide appropriate referrals to other testing sites for clients outside of the serviceable age range. HIV testing may be offered to individuals age 13 and older without parental consent in Louisiana. Neither rapid tests nor OraSure confirmatory tests may be performed on persons under the age of 13, in accordance with manufacturers' instructions. Failure to comply with a manufacturer's instructions is a violation of a testing site's CLIA agreement. Therefore, persons 12 and younger must be referred to an early intervention clinic or pediatrician for proper medical attention and assessment of HIV infection.

7. All testing sites are required to develop and/or maintain written policies on crisis management, sobriety of clients to obtain services, and confidentiality. The CBO Manual should serve as the basis for those policies but should be supplemented with agency specific procedures and policies.

8. Organizations are responsible for obtaining the proper liability insurance coverage for rapid HIV testing. SHP may require proof of current and appropriate insurance prior to the approval of any rapid HIV testing activities.

9. Organizations must obtain a CLIA certificate independent of the public health laboratory for processing rapid HIV test kits. CLIA application fees are the responsibility of the organization. Instructions for completion are available through the OPH SHP Regional Coordinator. A copy of the agency's CLIA

certificate must be faxed to OPH SHP prior to the initiation of any rapid HIV testing activities.

10. Agencies conducting CRT must arrange for the proper disposal of biohazardous waste materials resulting from CRT activities. SHP will provide assistance with arranging proper disposal as needed. All used rapid testing devices and other testing materials that have come into contact with bodily fluids must be disposed of in biohazard waste material bags in accordance with local regulations for infectious waste disposal. Shipping and/or transporting of processed devices/vials outside approved testing areas is prohibited, unless stored in a sealed and clearly marked biohazard waste container and placed in a trunk or impermeable container to ensure no contact with personnel or other individuals in the event of an accident, etc.

2. Prerequisites for Testing Supplies

1. Testing sites contracted or approved to conduct rapid HIV testing will use INSTI, OraQuick, Uni-Gold and/or Clearview rapid testing devices – all technologies are CLIA waived, single-use, qualitative immunoassays to detect antibodies to HIV:

- The INSTI Rapid HIV-1 Anitbody Test consists of:
    - A single use testing device
    - 3 Solution vials
    - Disposable single use specimen collection pipettes
    - A sterile safety lancet
- The OraQuick ADVANCE Rapid HIV-1/2 Antibody Test consists of:
    - A single-use testing device and solution vial
    - A reusable test stand, and
    - Disposable single-use specimen collection loops.
- The Uni-Gold Rapid HIV-1/2 Antibody Test consists of:
    - A single-use testing device
    - A multi-use wash solution bottle (5.0ml)
    - Disposable pipettes for use with venipuncture whole blood and when running controls, and
    - Disposable finger stick sample collection and transfer pipettes for use with finger stick whole blood
- The Clearview Complete HIV-1/2 Antibody Test consists of:
    - A single-use testing device
    - A buffer vial attached to the testing device (350µL)
    - A sterile safety lancet
    - Adhesive Bandage

2. In addition, testing sites will also need:
    - INSTI, OraQuick, Uni-Gold and/or Clearview controls
    - Disposable absorbent workspace covers
    - Biohazard waste disposal bags
    - Latex/polyurethane/nitrile gloves
    - Alcohol prep pads (for blood specimen testing)
    - Sterile gauze (for blood specimen testing)
    - Sharps Container (for blood specimen testing only except Clearview Complete)

- Disposable Lancets (for blood specimen testing only except Clearview Complete)
- Thermometers (one for the area where test is processing, one for the storage area, one for the refrigerator/freezer, one for mobile sites)
- Freezer (INSTI only)
- Timers
- 10% bleach solution or FDA approved disinfectant
- HIV Test forms
- Informed Consent forms
- Adhesive Bandages (for blood specimen testing only except Clearview Complete)

3. Approved supplies will be provided by SHP for SHP funded CRT sites. Agencies may be required to obtain certain items at their own expense. CRT sites will not be provided additional funds for supplies or phlebotomy services. Up to date documentation of testing (including HIV Test forms) must be submitted to SHP before any additional supplies will be sent to a site.

3. Prerequisites for Quality Assurance of Test Kits

1. Running and documenting the results of external controls is the primary method to ensure the accuracy of rapid test devices. The respective controls for INSTI, OraQuick, Uni-Gold or Clearview verify that the rapid HIV antibody test is working properly and that users are able to properly administer and interpret the test.

2. CRT sites should run controls at least once each week before the start of testing that week – controls should additionally be run under any of the following conditions:

    i. Prior to a newly trained counselor conducting CRT with a patient/client
    ii. When opening a new test kit lot (lot numbers are printed on each box and device)
    iii. When a new shipment of test kits is received
    iv. If the temperature of the test kit storage area falls outside the acceptable storage temperature range
    v. If the temperature of the testing area falls outside of the acceptable storage temperature range
    vi. Prior to using test kits at remote locations (when the test kits are used outside of the area where they are stored), e.g., mobile vans, outreach testing, prisons/jails, drug treatment centers, etc.

3. If the results of any one of the control tests do not match the expected result, rerun all controls. If the repeated control test run produces unexpected results, do not use any tests from that entire lot number and notify the SHP Testing and Capacity Building Supervisor immediately.

4. Each rapid test device contains a built in control feature that demonstrates whether or not the test was conducted correctly. A control line or dot should appear in the control area (may be labeled “C” or “Control” depending on the specific device being used) of the test strip. The control line/dot must appear in

order for the respective test to be valid, whether or not there is a line/dot present in the test area of the test strip. The rapid test must be considered "invalid" when:

i. No control line/dot appears in the control area of the testing device
ii. A colored or flecked background in the result window makes it too difficult to read the result after the required processing time has elapsed
iii. If any of the lines are not inside the appropriate control or test line areas (does not apply to INSTI)
iv. The sample well is not completely red after adding a blood specimen (Uni-Gold tests only).

4. Prerequisites for CRT Staff/Personnel

1. All persons certified to conduct CRT must first attend the combined HIV Prevention Counseling and Rapid Testing training. Applications must be submitted online at www.hiv411.org. Any person who is confirmed to attend CT training but does not show up and does not cancel within 24 hours prior to the start of training, will not be given priority in future CT training. If this occurs twice within a 12 month period, then the person will not be allowed to attend any CT training for 2 years after the second missed training.

2. After completing the HIV Prevention Counseling and Rapid Testing training and receiving a certificate of completion, there are two additional steps.

    - First, a written test covering HIV prevention counseling, rapid testing skills, and protocol/paperwork must be passed. The dates, locations, and method of signing up for a class are outlined on www.hiv411.org.

    - Secondly, all persons conducting CRT must successfully complete an observation session with the Regional Prevention Coordinator or other SHP Prevention staff as arranged by the Prevention Coordinator (see attachment RT-3.8).

    Note: Each person has two opportunities to pass the written test and the counselor observation. If the person fails either the test or the observation twice, they must go through the entire process again, beginning with training. Also, the written test must be passed before the observation can be scheduled. Once the SHP Training Coordinator assigns a unique counselor number to the counselor, they are fully certified and may conduct CRT.

3. Counselors are required to be skilled in client-centered counseling. Additionally, counselors must be knowledgeable of a wide variety of harm/risk reduction activities and be comfortable demonstrating harm/risk reduction skills such as providing condom demonstrations. CBOs funded to conduct this intervention are responsible for screening potential counselors and reinforcing skills and knowledge with internal training activities.

4. Clients should only see one counselor – this includes giving test results and for any follow-up visits if possible. Consistency of the client and counselor relationship helps the client feel secure, reduces misunderstanding, and promotes the likelihood of effective risk reduction.

5. Agencies must identify, in writing, a designated Quality Assurance Coordinator using the Quality Assurance Coordinator Registration Form (see attachment RT-3.7) (typically the same person identified to CLIA as the laboratory director – this could be the Counseling and Testing Supervisor/Coordinator, Head Nurse, Prevention Manager, etc.). The Agency's rapid testing Quality Assurance Coordinator will be responsible for informing other staff on updates and/or revisions to the State of Louisiana Rapid HIV Testing and Prevention Counseling Quality Assurance Protocol as needed. The Quality Assurance Coordinator is also responsible for ensuring his/her agency is in 100% compliance with the quality assurance protocol including the proper use, storage and documentation of rapid testing devices/activities. This includes ensuring that all rapid testing logs are checked at least once per month. Quality Assurance Coordinators must be fully trained on the rapid testing device(s) being used at his/her agency and have sufficient experience with rapid testing (6 months experience rapid testing and at least 200 tests conducted for staff at established agencies – agencies not new to conducting rapid testing).

III. REQUIRED ACTIVITES DURING CRT SESSIONS

A. General Requirements for Conducting CRT Sessions

1. All agencies conducting CRT in Louisiana must model sessions with clients according to the format and guidelines that follow. The Regional Prevention Coordinator and the HIV Counseling and Testing Supervisor must approve any alternate model/process of conducting the CRT intervention. Agencies that want to use an alternate model/process of conducting CRT must submit detailed proposals along with any supporting evidence, in writing, to the Regional Prevention Coordinator. Agencies will be notified by SHP in writing whether or not it is acceptable for an alternate model/process of conducting the intervention (see Attachment RT-3.9 for one page model).
2. Universal precautions for the prevention of occupational exposure to HIV and other blood borne pathogens must be strictly adhered to at all times during CRT sessions.

B. *Required Activities Before the Rapid Test Begins Processing (Before Testing)*

1. Introduce yourself to the client. Give the client your name and welcome them to the agency.

2. Assess client's readiness to receive the results on the same day. Ask the client questions to determine their motivation for getting tested and what, if any, support system is in place.

3. Offer options for testing that are available. For oral fluid testing, ensure that the client has not chewed gum, eaten, or had anything to drink in the 15 minutes prior to collecting the oral fluid specimen. Also ensure that the client has not engaged in any oral care (flossing, brushing, etc) within 30 minutes of collecting the oral fluid specimen.

4. Describe the testing process, what type of specimen will be collected, how long the whole process will take, and what each of the three possible results mean. It is a part of informed consent for clients to understand what type of specimen will be taken from them, how long the rapid testing session will take, and that the three possible results are preliminary positive, negative, and invalid. Clients should also be informed what actions will take place after each of the results.

5. Explain to client that if a preliminary positive result is received, a second rapid test should be conducted. *According to the CDC, a very important part of counseling persons who have a reactive rapid HIV test result is to make sure they understand that the test result is preliminary, and further testing must be done before referring to medical care.* Clients must be asked how they would react to getting a preliminary positive result in a rapid time frame in order to determine if testing is beneficial at that time.

6. Persons who have identified themselves as HIV positive should not be retested with a rapid test. Individuals infected with HIV-1 and/or HIV-2 who take antiretroviral medication can produce false negative rapid test results under some circumstances. Self identified HIV infected persons should be referred to case management and/or medical care.

7. Inform the client that, should they test positive, they will be contacted by the Office of Public Health DIS for Partner Services. Emphasize that this is a free and confidential service OPH provides should the client want help in notifying partners of their exposure to HIV.

8. Offer anonymous and confidential options, and explain what each mean. Clients must be offered the option of anonymous or confidential HIV testing. This is in accordance with Louisiana law 1300.12 HIV –related testing; consent; exceptions, element E. Anonymous testing involves the use of no personal identifiers (i.e. last name, first name, or social security number) that would link an individual to his/her test result. Confidential testing indicates that a client is willing to provide personal identifiers (including a first and last name and at least one of the following: mailing address, e-mail address, or phone number) that can be used to link the individual to his/her rapid HIV test result. Confidential testing is strongly encouraged to facilitate the entry into follow-up medical services for individuals who have been identified as HIV infected and should be encouraged for all confirmatory testing. Persons testing anonymously cannot be contacted – they can only receive test results by keeping track of and presenting their “P” number, which corresponds to their HIV test form.

9. Obtain Informed Consent. It is required that written “Informed Consent” for HIV testing be obtained prior to clients receiving any HIV testing. It is recommended that clients testing anonymously write the HIV Test Form number on the bottom of the Informed Consent Form. Clients testing confidentially must sign their name. Disclosure of HIV test results is strictly governed by the State of Louisiana as noted on the reverse side of the consent form.

10. Provide appropriate subject information pamphlet for the rapid test being conducted. The FDA requires that all test subjects receive the “Subject Information” pamphlet produced by the manufacturer of the rapid test device being used prior to collecting a specimen for testing. These pamphlets are included in each box of the various rapid testing products. Contact your SHP Regional Coordinator for additional copies of these pamphlets.

11. Collect and run specimen **(*).** Testers must follow the instructions provided by the manufacturer of the rapid test device he/she will be using. In addition to manufacturer instructions, identifying stickers from the HIV Test form should be placed on the testing device (or on the developer solution vial for OraQuick tests) to ensure quality control. Not following the manufacturer’s instructions may result in inaccurate test results.

C. *Required Activities While the Rapid Test is Processing (During Testing) The following steps apply to testing with OraQuick, Clearview, and Uni-Gold when used as the first rapid test. *For those using INSTI as the first rapid test, collect the specimen and run that test after #3 below.*

1. Complete the HIV Test form-Part 1 as much as possible. Each rapid HIV test must be documented on the SHP HIV Test Form-Part 1 and test forms must be completed in their entirety and submitted to SHP on a weekly basis to be entered for reimbursement and analysis. Additional CRT supplies may not be provided until HIV test forms accounting for the previously shipped supplies are received by SHP.

2. Conduct Step 2 (Identify personal risk behavior) of the counseling process. Step 2 should explore previous risk-reduction efforts and identify successes and challenges in those efforts. Factors associated with continued risk behavior that might be important to explore include using drugs or alcohol before sexual activity, underestimating personal risk, perceiving that precautionary changes are not an accepted peer norm, perceiving limited self-efficacy for successful change efforts, receiving reinforcement for frequent unsafe practices (e.g., a negative HIV test result after risk behaviors), and perceiving that vulnerability is associated with "luck" or "fate".

3. Conduct Step 3 (Identify safer goal behaviors) of the counseling process. When considering safer goal behaviors (Step 3), counselors should focus on reducing the client's current risks and avoid discussions regarding HIV transmission modes and the meaning of HIV test results. However, when clients believe they have minimal HIV risk but describe more substantial risk, the counselor should discuss the HIV transmission risk associated with specific behaviors or activities the clients describe and then discuss lower-risk alternatives. For example, if clients indicate that they believe oral sex with a risky sex partner poses little or no HIV risk, the counselor can clarify that, although oral sex with an infected partner

might result in lower HIV transmission risk than anal sex, oral sex is not a risk-free behavior, particularly when commonly practiced. If clients indicate that they do not need to be concerned about HIV transmission among needle-sharing partners if they use clean needles, the counselor can clarify that HIV can be transmitted through the cooker, cotton, or water used by several persons sharing drugs. With newly identified or uninformed HIV-infected clients, the counselor should discuss HIV transmission risks associated with specific sexual or drug-use activities, including those in which the client might not be currently engaged. Although the optimal goal might be to eliminate HIV risk behaviors, small behavior changes can reduce the probability of acquiring or transmitting HIV. Behavioral risk-reduction steps should be acceptable to the client and appropriate to the client's situation. For clients with several high-risk behaviors, the counselor should help clients focus on reducing the most critical risk behaviors they are willing to commit to changing.

4. Continue to assess client readiness to receive result. Counselors have until the timer goes off, thus indicating the rapid test is finished processing, to assess whether the client is ready to receive same day test results. Once the counselor interprets/reads the test result, they must provide the test result to the client unless the client objects to receiving their results at that time. Counselors should not attempt to assess client's readiness once the test results have been interpreted/read (for example, asking the client again if he/she is ready for their results after going to read the results- this should be done before interpreting/reading the result).

D. Required Activities After the Rapid Test Has Finished Processing (After Testing)

1. Provide the test result to the client (see section *F. Specific Guidance on Delivering HIV Test Results* for more information).

2. Conduct Steps 4 (Create a client action plan), 5 (Offer referrals and provide support), and 6 (Summarize and Close). The action plan must be documented on the Risk Reduction Worksheet (Attachment RT-12).

3. Set up a follow-up appointment, if necessary, for those testing negative to get retested.

4. Provide condoms, other harm/risk reduction tools and appropriate literature.

5. Complete the remainder of HIV Test Form-Part 1.

6. Complete other documentation as needed

7. Correctly dispose of used testing supplies following universal precautions and safe work practices at all times.

F. *Specific Guidance on Delivering Rapid HIV Test Results*:

1. Preliminary Positive Rapid Test Result:

i. Accurately communicate results to client - the result shows signs of HIV antibodies and a second test must be done to be sure.
ii. Allow time for emotional response. Do <u>not</u> rush the client into conversation.
iii. Ensure the client understands what the result means.
iv. Assess client concerns.
v. It is mandatory to offer a second rapid test. <u>The second test must be a different rapid testing device than the first one used</u>. If the OraQuick is the second test performed, a whole blood specimen **MUST** be used (oral fluid specimens may not be used for the second test following a preliminary positive rapid result from another rapid test). 100 % of clients who have a reactive/preliminary positive rapid HIV test result must be offered a second rapid test and offered referrals to early intervention/medical care after receiving a second reactive test result. Conducting the second rapid test and delivering its result must be done in the same client visit.
    i. If the second rapid test is invalid, repeat the test again. If two invalids are received, the client should be referred to medical care.
    ii. If the second rapid test is negative, then clients should return one week later for retesting.
        1. For follow up testing, if the first rapid test is negative, no more testing is required.
        2. If the first rapid test is positive, follow normal procedures and conduct a second rapid test.
        3. A new Part 1 STD/HIV Test Form should be filled out when the client returns for testing. Retain the Part 1 form from the first test in the client file until the client returns for the follow-up testing one week later, and mail both test forms to SHP together.
        4. If the client does not return for the follow up test, mail the first Part 1 form to SHP, and mark on the Part 1 ‘Client did not return for follow up testing’.
vi. Review the client’s risk assessment and risk reduction plan.
vii. Emphasize the importance in taking health precautions while they wait to attend their first medical appointment.
viii. Negotiate additional referrals with client, including medical referrals and referrals to local HIV agency for other supportive services and case management.
ix. Remind clients that a DIS will contact them to assist with notifying partners of their possible exposure to HIV.
x. Conduct Partner Elicitation if trained to do so.

xi. Provide condoms and literature as deemed appropriate.
xii. HIV TEST FORM – PART 2 should be completed when the client receives a second reactive rapid test. Do not fill out a Part 2 form if the second rapid test is invalid or negative.

2. Negative Rapid Test Result:

i. Review with the client his/her risk assessment and risk reduction plan.
ii. Discuss plans for staying negative.
iii. Assess need to retest.
iv. Provide condoms and other harm/risk reduction tools and appropriate literature.
v. Assess the client's need for other referrals.
vi. Make sure client understands the window period and whether he/she needs to be retested at a later date.

3. **Invalid Rapid Test:**

i. Explain that there was a problem running the test, either related to the test device or the specimen collected.
ii. Assess client concerns and emotional response.
iii. Assure client that quality assurance procedures are in place.
iv. Collect new specimen and run it with new rapid test device or refer to a public health unit if the client refuses an additional rapid test.
v. Provide condoms, other harm/risk reduction tools and appropriate literature.
vi. Review the client's risk assessment and risk reduction plan. Emphasize the need to take same risk reduction precautions as established.
vii. Personally checked all QA logs before testing another client.

IV. REQUIRED DOCUMENTATION OF CRT ACTIVITIES

A. Send all required documentation/forms to:

Testing Department
Office of Public Health
1450 Poydras St., Suite 2136
New Orleans, LA 70112.

B. To insure proper confidentiality measures, forms must be enclosed in two envelopes and marked "confidential" on the inside envelope. Testing information should be addressed to the Office of Public Health without any reference to "HIV" and/or "AIDS" in either the sender's address or the recipient's address. Forms that are hand delivered will not be accepted unless they are enclosed in two envelopes and properly addressed.

C. The destruction of the HIV Test Forms and Informed Consent forms are to occur by shredding ONLY (cross-cut shredding is recommended). All testing forms related to a confidential test including (HIV Test forms, HIV Laboratory Requisition forms, Informed Consent forms) should be maintained for at least 7 years. All testing forms related to an Anonymous test (HIV Test forms, Laboratory Requisition forms,

Informed Consent forms) should be maintained for at least 3 years and then destroyed.

D. HIV Test Forms and Laboratory Requisition forms must not be faxed or e-mailed.

E. Timeline for Submission of all documentation that must be completed and/or submitted to SHP

1. **Weekly Submission:** The following documentation/forms must be sent to SHP at least weekly.

   i. **HIV Test form-Part 1:** The top white copy of the HIV Test form-Part 1 must be completed and submitted to SHP for each rapid HIV test conducted. This must be done at least weekly. The two carbon copies may be kept in the client file, or one can be kept and the other shredded or offered to the client. Instructions for completing the HIV Test form are available from the SHP Regional Coordinator.

   ii. **HIV Test form-Part 2:** This form is completed for every second test conducted after an initial reactive rapid test. It should be mailed to SHP along with the corresponding Part 1 form immediately after it is completed. For clients who do not stay to receive their first or second rapid test result, hold on to Part 2 NO LONGER than 10 working days before submitting it to SHP, and write in large letters across the top: **CLIENT LEFT BEFORE RESULT AND DID NOT RETURN.**

2. **As needed:** The following documentation should be submitted to SHP as needed.

   i. **Supply Order Form:** (Attachment RT-5) this form should be completed and faxed to SHP when supplies are needed. Please allow at least 4 weeks for processing.

   ii. **CTR Rapid Site Assessment and Registration Form:** (Attachment RT-6) Prior to commencing rapid HIV testing activities at any site, this form must be completed by the Regional Coordinator. All sites must be registered and approved by SHP prior to the start of any rapid testing activities. Please allow up to four (4) weeks for approval of each site. A copy of this form should be kept on site.

3. **Maintain on site:** The following documentation must be maintained at each agency conducting HIV testing activities:

   i. **CLIA Waiver Certificate:** Each testing agency must obtain a CLIA waiver certificate prior to requesting approval for any rapid testing activities from the SHP. Information on obtaining a CLIA waiver certificate can be obtained from SHP Regional Coordinator or SHP Testing Supervisor. The agency's CLIA waiver certificate number must be included on every Site Registration Form submitted to SHP. Waivers must be current and a copy must be provided to the SHP prior to starting any rapid testing activities.

   ii. **Test Device Temperature Log:** (Attachment RT-3.1) Documentation of storage room temperature must be recorded daily for test kits. Again, the high

and low temperature for the test devices should be recorded every day that the office is open.

iii. **Control Kit Temperature Log:** (Attachment RT-3.2) Documentation of control kit storage temperature must be recorded daily for control kits. Again, the high and low temperature for the control kits should be recorded every day that the office is open.

iv. **Daily Rapid HIV Test Log:** (Attachment RT-3.3) All rapid tests conducted must be recorded on a daily test log. These logs are kept in agency files and may be requested by SHP at any time.

v. **Control Kit Log:** (Attachment RT-3.4) All control tests run at the testing site must be logged on the Control Log and signed by the Quality Assurance Supervisor. Any corrective action taken as a result of control testing must be documented on this log

vi. **Confidentiality Agreements:** All agency staff and volunteers must have a confidentiality agreement signed and on file at the testing agency.

vii. **Counselor Training and Counselor Number Certificates:** ONLY counselors certified by SHP in Rapid HIV Testing and Prevention Counseling are allowed to conduct the intervention in Louisiana. Staff and volunteers conducting rapid testing and prevention counseling activities are required to be skilled in client-centered counseling, collecting and processing rapid HIV test specimens accurately, and completing forms correctly. Skills and knowledge must be reinforced with participation in ongoing training and evaluation activities. The SHP requires that all counselors (volunteers and staff) become certified prior to conducting rapid HIV testing activities. Certificates must be stored in agency files.

viii. **Create An Agency Specific Quality Assurance Procedure Manual:** Agencies conducting CRT activities must have an agency specific quality assurance procedure manual available to certified counselors conducting CRT at all times. The CRT Protocol provided in the CBO manual (this document) should be used as the basis for an agency's specific quality assurance procedural manual but should be supplemented with specific procedures to follow related to client referrals, follow-up testing, discordant results, etc that are particular to each agency and location where CRT activities are conducted. Further, agencies are required to have written crisis intervention policies related to situations both involving personnel and clients.

ix. **Risk Reduction Worksheet**: (Attachment RT-3.12) Each client's risk reduction plan should be documented and kept in the confidential client file. It is acceptable for clients to receive a copy of their risk reduction plan.

V. CONSEQUENCES OF PROTOCOL VIOLATIONS

A. Failure to follow Louisiana rapid testing and prevention counseling protocol may result in a cessation of rapid testing activities until protocol issues are resolved or indefinitely. Protocol violations witnessed by or reported to SHP staff will be discussed with the testing site as soon as possible. Corrective action, if any, will be documented and submitted to the testing site and SHP Counseling and Testing Supervisor. An immediate halt of testing activities can occur when:

1. Confidentiality is compromised in the test processing area or through handling of documentation.
2. Quality assurance records/documents are not maintained as specified in this protocol
3. Informed consent is not obtained from clients prior to specimen collection

4. Completed HIV Test forms are not stored in a confidential manner and the specified copies are not sent to SHP on at least a weekly basis.
5. Rapid test kits or other testing supplies are distributed to and/or used by unauthorized entities or are unaccounted for.
6. Proper quality assurance of rapid test kits is not maintained (failure to keep adequate control, temperature and/or daily testing logs, etc.)
7. Testing is performed in locations not approved by SHP.
8. An agency's CLIA waiver expires without renewal.
9. Confirmatory testing is not offered to a client who has a preliminary positive rapid test result.
10. Documentation for clients who test positive for HIV is not filled out completely/correctly and/or submitted to SHP at least weekly.
11. Clients who test positive for HIV are not referred to appropriate HIV medical treatment services and/or follow-up on HIV medical care referrals is not made and/or documented.

B. According to Louisiana Law RS 40: 1300.13, community-based organizations conducting HIV testing services are required to follow all applicable HIV testing protocols established by the Office of Public Health STD/HIV Program.